

PATENT COOPERATION TREATY

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NOTIFICATION OF TRANSMITTAL OF
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EXAMINATION REPORT

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IMPORTANT NOTIFICATION

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Applicant
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1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCTAB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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still be within the scope of this invention. A curved catheter 118 may be useful, for example, in fluid exchange where the surrounding tissue tends to exhibit sharp curves, for example, in alveolar tissue. By incorporating a curved catheter 118 and/or a catheter 118 that is flexible, hence allows curvature to take place, damage to the tissue surrounding an alveolus may be reduced.

Catheter 118 with balloon extensions 122, or other extension embodiments, has application, for example, as a body ingress for insulin derivatives delivered to the body using, for example, an insulin pump. Additionally or alternatively, catheter 118 may be used for lavage of a body organ, wherein sterile fluids are introduced and/or evacuated for the purpose of control of infection. In these latter two applications, catheter 118 is, for example, three or more centimeters in length, based upon the thickness of the body tissue it must traverse in order to reach its targeted fluid exchange area.

In an embodiment of the invention, catheter 118 may have a larger bore, for example 4 millimeters or larger, to accommodate evacuation of exudative material that is highly viscous. Additionally or alternatively, catheter 118 may have a narrower bore, for example one millimeter or less, in order to provide a stream of fluid entering an organ with high pressure that breaks up an infectious nidus so that it can be more efficiently evacuated from the body.

Fig. 2D illustrates still another design of balloon extension 122 where the one or more extensions are narrow with tips 156 that press a wall of vein 130 when balloon extensions 122 are in an expanded state. This alternative embodiment allows fluid movement within the surrounding cavity even as balloon extensions 122 are expanded. Narrow tips 156 possibly provide an advantage in arterial fluid exchange when catheter 118 is used in an artery where collateral arterial blood flow is missing and/or compromised and occlusion of the artery can cause tissue damage due to lack of blood flow. Narrow tips 156 allow blood flow to proceed even as balloon extensions 122 are extended.

Fig. 3 shows another embodiment of the present invention 300 where the extensions are one or more deformable extensions 312 that push walls of vein 130 away from catheter inlet 134, removing and/or displacing blockages, for example those noted above, allowing fluid intake through catheter 118. Deformable extensions 312 have a deformation area 340 that maintains one position near catheter 118 and a second position, away from catheter 118 which pushes wall of vein 130 away from tip of catheter 134. While two end positions are provided in some embodiments of the invention, for example, using suitable mechanical stops on catheter 118, in other embodiments of the invention multiple (or continuous) intermediate

CLAIMS

1. Apparatus adapted to be placed through a body tissue and implanted in a vein for the purpose of intake of fluid through an aperture thereof, comprising:
 - 5 a hollow tube defining at least one aperture; and
 - at least one extension operative to be at at least two positions with respect to said aperture, a first position near said aperture and a second position in which at least part of said extension extends away from said aperture, wherein extension of said at least one extension from said first position to said second position in relation to said aperture is operative to
 - 10 displace at least one fluid intake impediment from said aperture.
2. Apparatus according to claim 1 wherein said aperture comprises a front opening at a front end of said tube.
- 15 3. Apparatus according to claim 1, wherein said aperture comprises one or more side openings in a side of said tube.
4. Apparatus according to claim 1 wherein said aperture comprises at least one front opening at a front end of said tube and at least one side opening in a side of said tube.
- 20 5. Apparatus according to any of the preceding claims wherein said impediment comprises an aggregate of solid material.
6. Apparatus according to any of the preceding claims wherein said impediment is down-
- 25 flow from said hollow tube.
7. Apparatus according to any of the preceding claims wherein said impediment is at least partly within said hollow tube.
- 30 8. Apparatus according to any of the preceding claims wherein said impediment comprises a venous valve.

9. Apparatus according to any of the preceding claims wherein said impediment comprises body tissue.
10. Apparatus according to claim 9 wherein said body tissue is inflamed.
- 5 11. Apparatus of any of the preceding claims wherein said hollow tube is adapted to be implanted in a vein for the purpose of unimpeded intake of fluid for a period of one or more weeks.
- 10 12. Apparatus of any of the preceding claims wherein said hollow tube is adapted to be implanted in a vein for the purpose of unimpeded intake of fluid for a period of one or more months.
- 15 13. Apparatus according to any of the preceding claims, comprising an activating mechanism.
14. Apparatus according to claim 13 wherein said activating mechanism causes said extensions to extend from said first position to said second position.
- 20 15. Apparatus according to claim 13 wherein said activating mechanism causes said extensions to un-extend from said second position to said first position.
- 25 16. Apparatus according to claim 13 wherein said activating mechanism comprises a locking mechanism that, when unlocked, allows said extensions to extend from said first position to said second position.
17. Apparatus according to any of claims 13-16 wherein at least a portion of said activating mechanism is external to said body tissue.
- 30 18. Apparatus according to any of claims 13-17 wherein a portion of said one or more extensions is external to said body tissue.

19. Apparatus according to any of claims 13-18 wherein the activating mechanism is manually activated.
20. Apparatus according to any of the preceding claims wherein the activating mechanism is automatically activated.
21. Apparatus according to any of the preceding claims wherein said extension of said extensions occurs prior to said fluid withdrawal.
22. Apparatus according to any of the preceding claims wherein said extension of said extensions occurs during said fluid withdrawal.
23. Apparatus according to any of the preceding claims wherein said extension of said extensions occurs following said fluid withdrawal.
24. Apparatus according to any of the preceding claims wherein at least some extension of said extensions takes place irrespective of fluid exchange.
25. Apparatus according to any of the preceding claims wherein at least part of said one or more extensions, overlaps a front end of said tube when said extensions are in a first position.
26. Apparatus according to any of the preceding claims wherein said at least one aperture is covered by said one or more extensions in said first position.
27. Apparatus according to any of the preceding claims wherein said apertures are arranged to be covered in said first position.
28. Apparatus according to any of the preceding claims wherein one or more of said catheter and said extensions comprise a material that prevents or retards aggregation of solids from said body fluid.
29. Apparatus according to any of the preceding claims wherein one or more of said catheter and said extensions comprise a material that prevents or retards clot formation.

30. Apparatus according to any of the preceding claims wherein one or more of said catheter and said extensions comprise a material that prevents or retards body tissue inflammatory response.
- 5 31. Apparatus according to any of the preceding claims wherein one or more of said catheter and said extensions comprise a material that prevents or retards bacteria colonization.
32. Apparatus according to any of the preceding claims wherein the one or more extensions
10 comprise expendable elements.
33. Apparatus according to claim 32 wherein said one or more balloons expand when filled with expansion fluid.
- 15 34. Apparatus according to claim 33, comprising an activating mechanism including a reservoir containing expansion fluid connected to said one or more balloon extensions.
35. Apparatus according to any of claims 33-34 wherein said expansion fluid comprises a material that affects the formation of impediments and wherein said balloon is at least partly
20 permeable to said material.
36. Apparatus according to any of claims 1-31 wherein the one or more extensions comprise an extension with a deformable area.
- 25 37. Apparatus according to claim 36, wherein when said deformable area deforms, said extension extends from said first position to said second position.
38. Apparatus according to claim 36 or claim 37 wherein when said extension un-extends from said second position to said first position, said deformable area returns to its pre-
30 deformed state.
39. Apparatus according to any of claims 1-29 wherein the one or more extensions comprise resilient extensions.

40. Apparatus according to any of claims 1-29 or 36-39, comprising a sheath for selectively controlling an extension position of said extensions.

5 41. Apparatus according to claim 40, wherein when said at least one extension exits distally from said sheath they deflect radially.

42. Apparatus according to any of claims 1-29 or 36-39, comprising an extension tube of which said extensions form a distal section, wherein axial distal motion of said extension tube causes said extensions to extend.
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43. Apparatus according to claim 41, wherein a distal section of said extension tube is axially fixed to a front of said hollow tube and wherein said extension tube is slotted.

15 44. Apparatus according to any of the preceding claims, wherein said extensions are adapted for an arm vein.

45. Apparatus according to any of the preceding claims, wherein said extensions are adapted for a non-vein vessel.
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46. Apparatus according to any of the preceding claims, wherein said positions are axially displaced.

47. Apparatus according to any of the preceding claims, wherein said positions are radially displaced.
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